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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,827	03/26/2007	Kazumi Koga	BY0033P	9797
210	7590	01/13/2009	EXAMINER	
MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907			LANDSMAN, ROBERT S	
ART UNIT		PAPER NUMBER		
1647				
MAIL DATE		DELIVERY MODE		
01/13/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/577,827	KOGA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 08 December 2008.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 2-6,8 and 9 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) 2-6 is/are allowed.

6) Claim(s) 8 and 9 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_.

## DETAILED ACTION

In processing this application for allowance, certain issues have been raised by the Examiner. Therefore, the finality of the Office Action mailed 9/19/08 has been withdrawn and prosecution on the merits continues.

### ***1. Formal Matters***

- A. The Amendment filed 12/8/08 has been entered into the record.
- B. Claims 2-6, 8 and 9 are pending and are the subject of this Office Action.

### ***2. Claim Objections***

- A. The syntax of claim 8 can be improved by replacing the phrase "one or between 2 and 6" to "one to 6", or "fewer than 6", etc. It is noted, however, that "between 2 and 6", in absence of a definition in the specification, can mean "3 to 5" since "between" is not inclusive of "2" and "6". If Applicants intend to include "6" then the claim could be amended to recite, for example, "fewer than 7" - **without adding new matter (see the new matter rejection below)**.
- B. The syntax of claim 9 could be improved by reciting "A method of evaluating a compound..."

### ***3. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement***

- A. The rejection of claims 3, 6 and 9 under 35 USC 1112, first paragraph, has been withdrawn in view of Applicants' amendments to the claims to recite a functional limitation and to recite that the cells are isolated.

### ***4. Claim Rejections - 35 USC § 112, first paragraph – new matter***

- A. Claim 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite "one, or

between 2 and 6." Though no issue was raised with this amendment filed 8/1/08, it has since been determined that no support is found for this limitation in the specification **Therefore, this is a new matter rejection.**

**5. Claim Rejections - 35 USC § 112, second paragraph**

A. The rejection of claims 8 and 9 under 35 USC 1112, second paragraph, has been withdrawn in view of Applicants' amendments to the claims to either delete the phrase "ORL1 activity" (claim 8) or to provide a specific activity (claim 9).

B. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a conclusion step stating what the desired endpoint or outcome of the method is - for example in part (a) - "wherein specific binding of the test compound identifies it as an ORL1 ligand" and part (b) - "wherein a change in activity of the transducer in the presence of the compound indicated that the compound is a modulator of ORL1 activity" – without adding new matter.

**6. Conclusion**

A. Claims 2-6 are allowable.

**Advisory information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman, Ph.D. whose telephone number is (571) 272-0888. The examiner can normally be reached on M-F 10 AM – 6:30 PM (eastern).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Robert Landsman/  
Primary Examiner, Art Unit 1647